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D SALAMANCA



HR EXCELLENCE IN RESEARCH

# Manual of Good Practice in Research

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VICE-RECTORATE FOR RESEARCH





## Foreword

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The world we live in today is inconceivable without the contributions of science and the technological development derived from them. All scientific disciplines, including the natural sciences, social sciences, and humanities, have contributed to the advancement of knowledge, and with it, to social and technological progress. In short, scientific research is a fundamental and essential tool for the development of knowledge-based societies and, as a human activity, it must be subject to ethical principles that ensure that it remains at the service of society so that it can develop by increasing its well-being, justice, and equality.

In its Statutes, the University of Salamanca (USAL) establishes as one of its main aims the contribution to the broadening of knowledge in all spheres of study. In this way, the University of Salamanca presents research as one of its most important areas of activity, becoming the basis for teaching and as a means for the scientific, technical, and cultural development of society. Given the University of Salamanca's involvement in research, and with the aim of ensuring that its activity in this field complies with the ethical guidelines and principles that ensure its quality, the Governing Bodies of the USAL have proposed the need to formally express this commitment to society.

The result of this initiative is the present Manual of Good Practice in Scientific Research. This document is framed within the research activity of the USAL, and is aimed at the researchers, as well as the support staff, the rest of the institutions involved and the funding agencies. This Manual contains a compendium of rules, commitments and recommendations aimed at ensuring the quality of scientific research and knowledge transfer through its execution based on the principles of freedom, responsibility, honesty, transparency, rigour, and the search for the common good. In this way, its effective response to social demands is ensured, improving and perpetuating society's confidence in this institution as a promoter of knowledge and technological progress. It should be borne in mind that in no case does a Manual of Good Practice replace the legislation in force but should be understood as a complementary guide.

This manual is based on the ethical principles that have been widely agreed by the scientific community, as set out in the European Code of Conduct for Integrity in Research promulgated by the European Federation of Academies of Sciences and

Humanities (ALLEA), the Brussels Declaration on Ethics and Principles for Science and Social Policy Making, the Singapore and Montreal Declarations on Research Integrity, the UNESCO Declaration on Science and the Use of Scientific Knowledge, the Code of Good Scientific Practice of the Spanish National Research Council and the National Declaration on Scientific Integrity of the Conference of Rectors of Spanish Universities. Other documents that have served as guidelines for the elaboration of this manual are listed in the first section of **Annex I**.

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The present edition of the Manual of Good Practice in Research was reviewed and positively informed by the Research Council of the University of Salamanca, in the session held on 16 of July; 2021.

## Contents

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|           |   |           |
|-----------|---|-----------|
| <b>1.</b> | <b>Objectives and Scope of Application .....</b>                        | <b>8</b>  |
| <b>2.</b> | <b>Values and Principles of Research .....</b>                          | <b>10</b> |
| <b>3.</b> | <b>Planning and Development of the Research.....</b>                    | <b>12</b> |
| 3.1       | Project planning .....  | 12        |
| 3.2       | Procedures and methodology .....  | 15        |
| 3.3       | Environment, infrastructures, and equipment.....                        | 15        |
| 3.4       | Management of funding.....  | 17        |
| 3.5       | Auditing and monitoring.....  | 17        |
| 3.6       | Safety, health, and procedures or potentially hazardous materials ..... | 18        |
| 3.7       | Collaborative research .....  | 19        |
| <b>4.</b> | <b>Respect for people, Heritage and the Environment .....</b>           | <b>22</b> |
| 4.1       | General aspects.....  | 22        |
| 4.2       | Experimentation on humans and human biological samples.....             | 23        |
| 4.3       | Animal experimentation.....   | 24        |
| 4.4       | Experimentation in heritage or natural environment.....                 | 25        |
| <b>5.</b> | <b>Managing Data and Materials Generated in Research.....</b>           | <b>26</b> |
| 5.1       | Data collection.....  | 26        |
| 5.2       | Ownership, custody and storage.....                                     | 27        |
| 5.3       | Access to and use of data .....   | 28        |
| <b>6.</b> | <b>Knowledge Transfer and Scientific Communication.....</b>             | <b>30</b> |
| 6.1       | General aspects.....  | 30        |
| 6.2       | Exploitable results.....  | 32        |
| 6.3       | Authorship and signature of written communications .....                | 33        |
| 6.4       | Open access philosophy.....   | 35        |
| 6.5       | Popular dissemination and outreach .....                                | 35        |
| <b>7.</b> | <b>Research Staff.....</b>  | <b>37</b> |
| 7.1       | Structure of research groups. Leadership and cooperation .....          | 37        |
| 7.2       | Recruitment, promotion, and evaluation .....                            | 38        |
| 7.3       | Training and supervision of the trainee researcher.....                 | 39        |
| <b>8.</b> | <b>Review and Evaluation Activities .....</b>                           | <b>43</b> |
| 8.1       | General aspects.....  | 43        |
| 8.2       | Peer review of publications and project evaluation .....                | 44        |
| 8.3       | Evaluation of projects and protocols.....                               | 44        |
| 8.4       | Assessment of applications.....   | 45        |

|   |           |
|---|-----------|
| <b>9. The Institutional Environment .....</b>                   | <b>46</b> |
| 9.1 Institutional commitment .....                              | 46        |
| 9.2 Action contrary to the manual and conflict resolution ..... | 48        |
| 9.3 Research Ethics Committee.....                              | 49        |
| 9.4 Dissemination, revision and updating of the manual .....    | 50        |

**ANNEXES**

|   |           |
|---|-----------|
| <b>Annex I.Reference Documents .....</b>          | <b>52</b> |
| Documents on which this manual is based .....     | 52        |
| Other institutional standards and guidelines..... | 53        |
| National laws and regulations.....                | 54        |
| Clinical research policy.....                     | 55        |
| Other references.....                             | 55        |

# 1. Objectives and Scope of Application

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In accordance with its Statutes<sup>1</sup>, the expansion of knowledge through scientific research is, together with teaching, one of the most important areas of activity of the University of Salamanca<sup>2</sup>. The main purpose of this document is to guide the behaviour of research practice towards compliance with the basic principles of quality and integrity within the USAL.

The specific objectives of this Manual of Good Practice in Research are:

- ▶ To pursue excellence and quality in scientific research carried out at the USAL by establishing guidelines for good behaviour based on the principles of freedom, transparency, honesty, rigour, and responsibility.
- ▶ To raise awareness of ethical issues related to research, and promote respect for people, animals, the environment, and heritage.
- ▶ To ensure a commitment to quality training for researchers at an early stage of their scientific career.
- ▶ To raise awareness of conflicts of interest and limit situations where they may occur in the field of research.
- ▶ To promote the dissemination of research results to the general public.
- ▶ To serve as a guide for the mediation and resolution of conflicts arising from bad scientific practices.

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<sup>1</sup> Art. 2 and Art. 110 of [the Statutes of the University of Salamanca](#) 

<sup>2</sup> From now on "USAL".

This Manual of Good Practice in Research involves a wide range of professionals, services, and administrative and management units. It applies to the following agents:

- ▶ The institution itself (USAL). The university must provide its researchers with the institutional environment that allows them to put these good practices into action, ensure that the manual is periodically reviewed, make sure that the rest of the agents to whom it is applicable are aware of it and can easily access it, and provide the means to ensure that it is effectively complied with.
- ▶ The research staff, both in the pre-doctoral and post-doctoral stages, and civil servants, as well as external visiting researchers who join on a temporary basis.
- ▶ Staff attached to the Departments of the Faculties and University Schools.
- ▶ Staff belonging to the University Research Institutes and USAL's specialised centres.
- ▶ The staff of the University Hospital of Salamanca and other health establishments, when they carry out research tasks in agreements signed by the USAL<sup>3</sup>.
- ▶ The Departments, Faculties and University Schools when the development of the research carried out therein may be affected by its management and direction.
- ▶ Any unit or service of the USAL whose activity is accessory to the development of research activity.
- ▶ Any unit or service of the USAL that performs scientific dissemination work to the general public.
- ▶ Any unit or service of the USAL that carries out educational work for research staff.

Finally, this manual aims to involve the scientific community of the USAL in the institution's improvement and promotion, through its periodic review, updating and approval.

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<sup>3</sup> Art. 26.2 of the [Statutes of the USAL](#) 

## 2. Values and Principles of Research

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The standards, commitments and recommendations that constitute the good practices contained in this manual are based on fundamental principles of research integrity.

These principles are:

- ▶ **Freedom** of the researcher<sup>4</sup>. Researchers should be independent in associating with other researchers with whom they carry out their work and in carrying out their research activity in the field of knowledge and under the methodology of their choice, free from external coercion or interests, and provided that all other principles are respected.
- ▶ **Rigour** in all stages of the research process, in such a way as to guarantee the reliability of the results produced and the knowledge generated:
  - Prior to the development of the research, in the design and planning of protocols, experimental methods or theoretical models.
  - During the development of the research, in the application of the methodology and protocols, in the analysis of the data and results, and in the communication to the scientific community.
  - In peer-review processes, in order to contribute to the quality of the publications of external researchers.
- ▶ **Responsibility** in the exercise of scientific and supervisory activity, consisting of the following commitments on the part of researchers:

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<sup>4</sup> Freedom in research is included in the [Statutes of the USAL](#) in Art. 3.

- To conduct research that is relevant to society (offering answers or solutions to questions or demands of their environment) or of academic interest (in the case of the development of basic or fundamental research lines).
- To offer quality research training when acting as supervisors in charge of Research Staff in Training.
- To take responsibility for the veracity and authenticity of the results on which they hold authorship.
- To carry out their research projects in accordance with the initial plan, especially when there is a commitment of accountability with public funding bodies.
- To make efficient use of human, financial and material resources.
- To decline involvement in activities where there may be a conflict of interest.
- ▶ **Integrity** and **honesty**. These should be manifested in a number of ways:
  - Presenting and acknowledging the limitations of one's own research.
  - Avoiding bias and acting fairly when reviewing and evaluating others'.
  - Acknowledging the contributions of the different members of the research team, and in general, of any other researcher, whose contributions have been of relevance to the work.
  - Valuing previous contributions to the state of the art in the context of one's own research.
- ▶ **Respect**, directed towards fellow professionals, and especially towards people, living beings, the environment and ecosystems, or heritage when these may be the subject of research or when they may be indirectly affected by the research.
- ▶ **Transparency** which, through accountability for research activity, provides evidence that the other principles have been respected:
  - Promoting scientific communication, facilitating access to data, methodologies and protocols that allow reproducibility by other research teams.
  - Addressing issues of ethical conflict (such as the processing of personal data, research involving human or other living beings, etc.) in accordance with the regulations in force and through the relevant committees.
  - Providing precise economic traceability and exhaustive monitoring of the development of research projects subsidised by the different public funding bodies.
  - Complying with the principles of publicity, transparency and merit in the selection processes for research staff.
  - Declaring conflicts of interest.

## 3. Planning and Development of the Research

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Rigour in research must start from the very moment a new hypothesis and its consequences are put forward. Thorough planning of research projects, including the review of the state of the art, the hypothesis statement, the expected results, the detailed and thorough design of procedures, or the resources required, is key to the subsequent optimal development of the work leading to results. This section sets out guidelines for comprehensive research planning and establishes essential good practice in matters relating to the organisation of research procedures, project monitoring, use of resources and funding, and health and safety.

### 3.1 Project planning

- 3.1.1 No external interest or source of funding should condition the design of a project or its development. Nor should the freedom and integrity of the researchers be compromised.
- 3.1.2 Research projects shall be planned prior to the start of their execution, and this planning shall be set out in a single document called a *research protocol*. This protocol is the research team's basic document. Its content shall include at least:
  - 3.1.2-a) The demand for knowledge or applications to which the project responds, contrasting the relevance of the problem.
  - 3.1.2-b) An exhaustive bibliographical review of the state of the art in the field concerning the project that justifies the starting hypothesis and the methodology used.

- 3.1.2-c) One (or more) hypothesis about the results to be obtained, supported by the scientific foundations set out in the previous section.
  - 3.1.2-d) The specific objectives of the project, which may be subdivided into partial objectives, deriving directly from the hypotheses, and serving as a basis and justification for the resources and methodologies proposed.
  - 3.1.2-e) The potential applications and the means of dissemination of the results obtained. Also, if they exist, the potential misuses to which the expected results could give rise.
  - 3.1.2-f) The necessary resources, including human and material resources, spaces, facilities, infrastructures, laboratory equipment and instruments, IT resources, health and safety equipment, etc. Those to be supplied or belonging to third parties must be expressly indicated.
  - 3.1.2-g) The methodology and procedures for achieving the proposed results. These should be consistent with the resources foreseen.
  - 3.1.2-h) A compilation of the specific regulations and legislation applicable to the activities of collection, processing, storage and destruction of samples and data (e.g., in the consultation of personal data).
  - 3.1.2-i) A plan for the collection, custody, storage and, where appropriate, destruction of data and samples. It should include, if necessary, a list of the specific infrastructures necessary to ensure their storage and preservation in accordance with the requirements of the regulations compiled in the previous point.
  - 3.1.2-j) The planning of the project in phases, including the scheduling of tasks on a timetable, detailing the interdependence between them, and the time allocation of material and human resources.
  - 3.1.2-k) An approximate budget breakdown.
- 3.1.3** Its content must be clear, and its wording must facilitate its understanding by the project evaluators, the researchers and the technicians involved in its implementation. In addition, its structure should allow linking the different phases, as well as providing consistency and coherence to the project.
- 3.1.4** The research protocols must be sufficiently detailed and complete so that other experts in the field can carry out the same project in order to assess the validity of their methods and the reliability of the results derived.
- 3.1.5** Research protocols affected by the assumptions set out in **4.1.1** must be assessed and approved by the Research Ethics Committee (**4.1.4** and **9.3**).
- 3.1.6** There is no justification whatsoever for carrying out research outside a research protocol, especially those involving human subjects or their samples, or animals as the object of study.
- 3.1.7** In special circumstances where research must be started urgently (e.g., due to safety or public health concerns), simplified protocols may be drawn up, which must in any case be approved in the same way as ordinary protocols.

- 3.1.8** When the development of a project raises a new issue not covered by the protocol, the research protocol should be expanded or a new one created to address these issues.
- 3.1.9** The research protocol is the responsibility of the principal investigator, who acts as the coordinator of the working team, and may also participate in the development of the protocol.
- 3.1.10** In applications for grants and funding, the person responsible for the protocol shall also be responsible for the veracity of the existence and/or granting of the use of the available or allocated resources.
- 3.1.11** The protocols shall be consistent with those described in the reports relating to the applications for funding with which the projects are expected to be supported.
- 3.1.12** The planning of the projects should also foresee the communication of results, both in the form of publication of scientific articles and the presentation of results at conferences and workshops.
- 3.1.13** It is advisable to include the potential appeal of the project for the dissemination of results to the general public.
- 3.1.14** The design of a protocol must include an assessment of the risks implicit in the proposed methodologies and the tasks to be carried out, both for the researchers themselves and for society, people, living beings, ecosystems or heritage that could participate as subjects of study or be potentially affected. Where appropriate, measures will be proposed to minimise them.
- 3.1.15** Potential illicit uses to which the expected results could give rise should also be analysed.
- 3.1.16** The research protocol itself should establish its own monitoring and review measures.
- 3.1.17** In projects planned in collaboration with different groups or institutions, it is advisable to formalise in writing an agreement that sets out the terms on which the different parties agree to collaborate. To this end, a *collaboration agreement* should be included that covers:
- 3.1.17-a)** All aspects of the research plan envisaged in the framework of the joint collaboration.
  - 3.1.17-b)** The explicit distribution of the responsibilities, rights and duties of the participating groups or institutions in relation to the tasks to be developed and the results to be obtained.
  - 3.1.17-c)** The policies of ownership, custody, storage and access of the data or samples obtained.
  - 3.1.17-d)** Criteria for updating the development of the studies among the different participating groups or centres.
  - 3.1.17-e)** Policies on possible commercial implications, exploitation of results, and funding.

## 3.2 Procedures and methodology

- 3.2.1 The procedures and methodology envisaged should have validity supported by evidence from previous use.
- 3.2.2 In the event that the plan proposes novel procedures and methodologies, or involves the use of previously untested technologies, the protocol must include the procedure for their implementation, testing and validation where the researchers demonstrate their reliability by means of evidence. Validation of these procedures should be considered as an objective in itself.
- 3.2.3 All procedures and protocols used in research should be adequately documented and referenced to facilitate further review.
- 3.2.4 The specific application of a procedure or protocol in the context of a research plan should reflect the specific objectives pursued, detailing, in addition to its design, the subjects or samples, the variables to be observed, data collection, and possible limitations.
- 3.2.5 Experimental methods should be designed to make the best use of resources without sacrificing the reliability of the results.
- 3.2.6 Research projects and protocols should not be secret. However, for competitive reasons, research protocols may be kept confidential during the course of the project and should be made public at the reporting stage in order to encourage reproducibility of results by other researchers.
- 3.2.7 During the development of the protocols, the research team will keep, as rigorously and in as much detail as possible, a record of the production conditions, the possible contingencies or difficulties that may arise during the execution of the work, and as much information as it considers necessary for the achievement of the objectives, in order to ensure the traceability of the data and results obtained.

## 3.3 Environment, infrastructures, and equipment

- 3.3.1 The USAL is responsible for providing, to the extent of its possibilities, the environment, spaces, infrastructures, and facilities necessary and appropriate for carrying out research and teaching activities in conditions of safety, health and other conditions that guarantee the viability of its research<sup>5</sup>.
- 3.3.2 The use of USAL equipment and infrastructures in projects developed in collaboration with other institutions or entities must be subject to contracts or agreements that recognise the participation of the USAL in the respective projects.

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<sup>5</sup> This does not include specific equipment for obtaining research results but does include the provision of spaces and infrastructures necessary for their installation and operation.

- 3.3.3** The conditions of use of USAL equipment and infrastructures in projects developed in collaboration with private entities must be clearly defined contractually in the respective projects.
- 3.3.4** During the design of the protocols and procedures foreseen in a research project, the use of infrastructures or facilities that are not for exclusive use must be considered, requesting a prior agreement for use with the person responsible for the equipment, centre or space planned.
- 3.3.5** Researchers shall be responsible for ensuring that the use of infrastructures and equipment is devoted to the activities foreseen in the research plans or to the institutional purposes of the university.
- 3.3.6** Furthermore, their use must be carried out in a responsible manner, ensuring an efficient use focused on the established objectives and avoiding use outside the research itself.
- 3.3.7** The acquisition of equipment will be carried out in accordance with the regulations of the USAL, and of its Faculties, Departments, Centres and Research Institutes, depending on where they are to be integrated.
- 3.3.8** When projects are financed by private entities, the policy (ownership and rights) regarding the use of the means, equipment and infrastructures acquired must be agreed in writing.
- 3.3.9** Principal investigators and those responsible for infrastructure, facilities and equipment shall ensure that personnel using such equipment are adequately trained and aware of the safety rules relating to the handling of such equipment and the work they intend to carry out.
- 3.3.10** In the event that in the same space or facility (e.g., a laboratory), researchers concur in carrying out different tasks, all of them shall be made aware of the safety measures relating to each of the tasks.
- 3.3.11** Safety instructions, measures and protocols for equipment and facilities shall be available in written form for consultation.
- 3.3.12** Before using specialised equipment, or entering a laboratory, researchers and students should be given a basic briefing on safety procedures for the use of laboratory equipment and products (see **3.6.4**).
- 3.3.13** The facilities, equipment and spaces belonging to the USAL, including its Research Centres and Institutes, will be maintained in accordance with the particular needs, so as to guarantee the safety of their users and the reliability of the results obtained with them.
- 3.3.14** Researchers who use facilities, equipment, or spaces outside the USAL shall demand from the responsible bodies the necessary conditions and actions to carry out their work reliably and safely.
- 3.3.15** Researchers have the duty to make careful use of the facilities and equipment in order to ensure their proper conservation, correct functioning and safety.
- 3.3.16** Researchers have the duty to inform the person or body responsible for the improper functioning of equipment or facilities, whether or not they belong to the USAL.

**3.3.17** Coordination in the use of equipment and means acquired or infrastructures installed with the funding of a completed research project will be the responsibility of the research group to which the responsible researcher belongs, who will become the coordinator of the use of these resources when the project ends, except in cases where another previously established criterion prevails.

## **3.4 Management of funding**

- 3.4.1** The USAL must ensure, through its research management units and services, compliance with the economic terms and conditions applicable to any grant or related research contract.
- 3.4.2** Research staff must facilitate the monitoring and supervision of the financial management of research projects and comply with the guidelines established by the USAL in this area.
- 3.4.3** Research project staff must agree on the most efficient and ethical use of funds requested or allocated for the implementation of a research project.
- 3.4.4** Funds obtained through funding programmes will be used in accordance with the conditions established in the corresponding call or agreement, which must have been previously signed by the Principal Investigator.
- 3.4.5** The Principal Investigator is responsible both for ensuring compliance with the clauses established with the funding entity and for informing the rest of the working team about them. Likewise, he/she is responsible for any technical or financial circumstance that may affect the development of the project.
- 3.4.6** The funds allocated to a project must be used strictly for the execution of the tasks described in the project's grant memorandum. Where funding bodies request justifications for the use of funds, these must be met within the designated time frames.
- 3.4.7** If during the course of a project changes to the protocol are foreseen that may significantly disrupt the budgetary programming, the Principal Investigator must notify the funding body of this fact.
- 3.4.8** Where a project has funding from several sources, the USAL staff designated to coordinate the project will ensure that there are no conflicts between the requirements and conditions of all funding bodies.

## **3.5 Auditing and monitoring**

- 3.5.1** The USAL may subject research projects carried out on its premises to monitoring and auditing to ensure that they are carried out in accordance with the agreed ethical and regulatory requirements. For its part, the USAL is responsible for ensuring that the staff conducting these audits are competent and have the necessary resources. The research staff in charge of the project shall facilitate these auditing and control tasks.

- 3.5.2 During the execution of a project, periodic reviews will be carried out on its development, checking the adequate fulfilment of the planning of tasks with the aim of making the necessary changes.
- 3.5.3 In the course of a project, the design of the procedures shall be borne in mind, ensuring that they are carried out in accordance with the protocol.
- 3.5.4 If, during the course of a project, the need for changes to procedures or protocols is identified, these changes and their justification shall be detailed in revised versions of the project plan, taking into account possible changes in the timing and budget foreseen.
- 3.5.5 Where such changes are major, the entities that provided financial support for the project shall be notified.
- 3.5.6 Protocols and procedures subject to ethical issues that need to be modified must be approved by the Research Ethics Committee in the same way as at the start of the project.
- 3.5.7 In the event of detecting, in the course of a project, the need to make new additions to the working team, the entities that were financing the project, if any, shall be informed of this new participation.

## 3.6 Safety, health, and procedures or potentially hazardous materials

Given the innovative nature of the research activity, it is common for there to be procedures contemplated in the protocols that involve the handling of materials, instruments, and machinery with associated risks. The statutes of the USAL<sup>6</sup> include the commitment of its teaching and research staff to carry out their work in safe conditions.

- 3.6.1 Research staff have the right and the duty to be informed about the regulations and health and safety policies in their work. To this end, the USAL offers researchers the Office for Health and Safety at Work.
- 3.6.2 The protocol should include a section on risk assessment that identifies the materials, instruments and tasks that pose specific risks to research staff, the university community, and the environment in general. It should also list and reference existing safety and prevention guidelines and protocols designed to mitigate these risks.
- 3.6.3 If such protocols do not exist, they must be developed prior to the start of the project, with the collaboration of the Office for Health and Safety at Work, if necessary.

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<sup>6</sup> Art. 141.k of the [Statutes of the USAL](#) 

- 3.6.4** Prior to the start of the tasks, the personnel involved in them and also those who could potentially be affected by the risks must be informed of the safety guidelines and protocols, with the principal investigator of the project being responsible for ensuring that this information reaches the interested parties. Special care should be taken to ensure that Trainee Research Staff have access to this information.
- 3.6.5** In addition, researchers must undertake to carry out their research in strict compliance with established health and safety protocols, and to report incidents that may pose a risk to the environment or to staff.
- 3.6.6** The Research Groups must ensure compliance with the previous sections, channelling information on the regulations, policies and protocols on health and safety related to the activities carried out by their members.
- 3.6.7** The University of Salamanca offers the University community, and its research staff in particular, the Office for Health and Safety at Work. Its functions are:
- 3.6.7-a)** To inform and train in terms of regulations and policies on health and safety at work.
  - 3.6.7-b)** To offer advice in the preparation of protocols subject to the use of hazardous materials, equipment, or infrastructures.
  - 3.6.7-c)** To serve as an advisory body for the approval and supervision of protocols that include procedures subject to potential biological and environmental risks.
  - 3.6.7-d)** To assess and approve these protocols.
  - 3.6.7-e)** To provide training in occupational risk prevention, health and safety at work, both transversal and specialised for specific sectors.
  - 3.6.7-f)** To ensure compliance with regulations and policies on health and safety at work by carrying out inspections and internal auditing activities.

## 3.7 Collaborative research

The principles of collaboration and exchange of ideas are fundamental values in the University of Salamanca's research policy. Therefore, the collaboration of the staff of the University of Salamanca, its Institutes and Centres with external entities, both public and private, is considered an effective way of tackling challenges that would otherwise be unmanageable. However, disagreements may arise in such collaborations due to the different interests of the parties involved. This section sets out good practices to prevent such circumstances.

- 3.7.1** Prior to the start of research projects in collaboration with other entities, an agreement shall be formalised in writing setting out the terms and conditions under which the collaboration will be carried out, establishing:
- 3.7.1-a)** An agreement on individual and common objectives.

- 3.7.1-b) An agreement on the use of facilities, equipment, and infrastructures of the USAL and the other entities.
  - 3.7.1-c) The rights of exploitation of results, intellectual and industrial property.
  - 3.7.1-d) Protocols for the dissemination and publication of results, including confidentiality agreements.
  - 3.7.1-e) Responsibilities in matters of ethics and security.
  - 3.7.1-f) Obligations regarding project monitoring and reporting, especially when public funding is involved.
  - 3.7.1-g) The conditions of occupational safety, work, or any other conditions that could affect the professional, physical, psychological, and moral well-being of USAL research staff.
  - 3.7.1-h) An agreement regarding the economic considerations derived from the industrial or commercial exploitation of the results.
- 3.7.2 In negotiations on the rights to exploit results, the primacy of the public interest must be borne in mind. Consequently, such agreements must be made in full transparency.
- 3.7.3 These agreements shall be established under the principle that the technical knowledge, materials, and results obtained in research at USAL facilities or by its researchers are the property of the USAL.
- 3.7.4 In anticipation of commercial or industrial interests derived from the results of the research, the USAL will make sure to avoid establishing unjustifiably long confidentiality policies that block the communication and publication of results.
- 3.7.5 When USAL researchers participate by contributing to the design and execution of a project promoted by industry, shared intellectual and industrial property agreements will be established. Periods of exclusive availability of the data and results will be negotiated for the company to assess their commercial or industrial interest.
- 3.7.6 Whatever the agreements on industrial or intellectual property, moral rights will be respected with regard to recognition as author or inventor.
- 3.7.7 USAL will provide legal support in order to preserve its previously existing intellectual and industrial property rights and to ensure the freedom of its researchers.
- 3.7.8 When the work carried out by a USAL research group contributes to the promotion and creation of technological companies, special attention will be paid to ensure that the use of USAL resources and infrastructures is not used in an abusive manner in favour of the interests of the participants in these companies.

**3.7.9** Personnel from outside the USAL who participate in projects managed by the USAL must have the authorisations in accordance with the university regulations of the USAL, and those of their own institution or company. The same criterion applies to USAL staff wishing to carry out tasks in collaboration with other institutions or companies.

## 4. Respect for people, Heritage and the Environment

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In many cases, research involves human or other living beings, ecosystems, the environment, or heritage. The aim of this section is to set out good practices to ensure that research involving any of these is carried out in accordance with the basic principle of respect.

### 4.1 General aspects

- 4.1.1 Project proposals that involve experimentation with people, human or animal biological samples, in the natural environment and its ecosystems or in heritage, must pay special attention to the ethical and legal aspects that are applicable, considering the regulations of the USAL itself, of local, regional, and national governments, and of the competent administrations in the places where the studies are carried out.
- 4.1.2 In this type of research, it is essential to carry out, in the design of the protocol, an exhaustive evaluation of the risks and the risk/potential benefit balance of the research.
- 4.1.3 The USAL puts at the disposal of the research staff the Research Ethics Committee (see 9.3) that assists in the compliance with the legal framework and in the elaboration of protocols that involve procedures of this nature.
- 4.1.4 Before their approval and implementation, protocols involving this type of methodology must necessarily receive a favourable report from the Research Ethics Committee of the USAL and other competent bodies in accordance with current legislation.

- 4.1.5 In turn, the participants and, especially, the principal investigators of this type of research projects must collaborate with the USAL Research Ethics Committee by making available to it any information regarding the protocols that may be requested.
- 4.1.6 After approval and during implementation, the applicable regulations and legislation should be kept in mind, and the principal investigator should be responsible for ensuring that this information reaches the personnel who are to carry out the procedures.
- 4.1.7 Proposals for research protocols should include a comprehensive collection of data from other similar studies in order to make an initial assessment of the evidence and potentially useful prior data that could avoid unnecessary testing. Particular attention should be paid to studies involving animals and humans.

## 4.2 Experimentation on humans and human biological samples

- 4.2.1 The primary consideration in any research involving human subjects or their biological samples as subjects or objects of study is the preservation of the rights, dignity, safety, and well-being of the participants over and above the obtaining of results.
- 4.2.2 The specific regulations on the treatment of samples for the purpose of genetic analysis and on research with human embryonic material shall be observed.
- 4.2.3 In the design of procedures involving human subjects or human biological samples, foreseeable risks to the study subject and to society must be considered, and they should only be initiated if the risk/potential benefit balance is favourable.
- 4.2.4 Clinical trials forming part of a research project must be authorised prior to their initiation by the centre where they are to take place and by an accredited Research Ethics Committee. It is also advisable to have a commitment of authorisation from the centre at the protocol development stage.
- 4.2.5 For the use of biological samples, which must be deposited in a collection of biological samples or in a biobank that meets the requirements established by law, there must be the express informed consent of those providing the samples (or, where appropriate, their guardians or legal proxies); the researcher in charge of taking the samples shall be responsible for this. The report should contain at least:
  - 4.2.5-a) The use to be made of their samples and data.
  - 4.2.5-b) The scope of the study.
  - 4.2.5-c) The potential risks and potential benefits of the research (both to themselves and others).

- 4.2.5-d) The selection criteria in the trial.
  - 4.2.5-e) The methodology.
  - 4.2.5-f) Subsequent storage plan and policy.
  - 4.2.5-g) Financial compensation, if any.
- 4.2.6 When investigators identify that biological samples or data collected for one project may be potentially useful in another, participants will be informed of this fact and permission will be granted for their use in trials outside the project for which they are reporting and requesting permission.
  - 4.2.7 Human biological samples and personal data from other projects will not be used or transferred if these data and samples do not have explicit consent for their use in research projects other than the one for which they were provided.
  - 4.2.8 Researchers should ensure that the confidentiality of all personal information collected from participants is respected in accordance with applicable data protection legislation.
  - 4.2.9 The plan for the custody and conservation of personal data collected in a project must pay special attention to ensuring the anonymity of the participants during their storage period.
  - 4.2.10 Subjects or entities participating in a USAL research project must be informed when the results are published if so requested.
  - 4.2.11 In projects in which it is planned to include USAL students as study subjects, they should only participate of their own free will, without acceptance or refusal to participate implying a penalty or academic advantage.

### 4.3 Animal experimentation

- 4.3.1 Animal experimentation shall comply with the provisions of RD 53/2013, conforming to the permissible purposes according to article 5, and shall only be performed with the prior approval of the competent authority of the Community of Castile and Leon.
- 4.3.2 Personnel working in procedures involving animal experimentation must have all the relevant accreditations established in the legislation.
- 4.3.3 The use of animals in authorised procedures for research and/or teaching must be accessible to society, as established in the COSCE (Confederation of Scientific Societies of Spain) agreement on transparency, to which USAL adheres.
- 4.3.4 It is the responsibility of researchers to notify the Research Ethics Committee if they detect mistreatment or practices that could cause unjustified harm to experimental animals.

- 4.3.5 Animal testing procedures must be designed following the 3Rs principles: the use of *replacements* when possible and feasible, *reduction* of the number of animals and optimisation of the amount of data obtained per specimen, and *refinement* of procedures to minimise pain, stress, injury and, in general, prolonged suffering.
- 4.3.6 Means shall be sought to mitigate pain caused to animals in tests, provided that this practice is less traumatic than the tests themselves, and that there are means compatible with the conduct and purpose of the experiment; the experiment shall be stopped if it would cause unnecessary pain, suffering or lasting harm during its course.
- 4.3.7 A register shall be kept of the animals used for experimental purposes, detailing the number and species of animals purchased and used, the establishment which supplied them and their final destination at the end of the experiment. This register shall be kept for at least three years after the end of the project and shall be available to the competent authority.
- 4.3.8 In addition, the identification details and the origin of any dog, cat or non-human primate shall be recorded in the register.
- 4.3.9 Researchers responsible for projects using animals shall ensure that their staff are informed about the ethical and legal requirements for working with animals in research and teaching and facilitate their access to related training activities.

## 4.4 Experimentation in heritage or natural environment

- 4.4.1 When research is conducted in natural or heritage sites (historical, archaeological, cultural, etc.), researchers should ensure that their activity does not interfere with planned care, maintenance, or restoration activities.
- 4.4.2 Interventions carried out in these places must be governed by the strictest international principles of respect for heritage, such as those established in the UNESCO Convention on the Protection of the World Cultural and Natural Heritage of 1972 in Paris.

## 5. Managing Data and Materials Generated in Research

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Data collection is one of the central activities in research where lack of rigour can seriously compromise the reliability of the results. Furthermore, these data have a high intrinsic value given their potential interest for other research, and therefore need to be properly stored and made accessible to other researchers. This section sets out good practices to ensure rigour in data collection, data traceability, as well as measures for data storage, custody, and access.

### 5.1 Data collection

- 5.1.1 Data collection will be carried out in compliance with the specific regulations applicable during the protocol design phase.
- 5.1.2 The research staff will collect all the data obtained in the research, including those that are not suitable for the achievement of the proposed objectives (for example, those coming from protocols in which faults have been detected, those obtained with incorrectly calibrated instrumentation and equipment or in inadequate conditions, etc.).
- 5.1.3 Together with the data, all the information that the researcher considers that may be significant in the process of obtaining these results, such as the time of collection, the identification of the samples, the configuration of the instruments, environmental or climatological conditions, etc., shall be collected. In addition, the investigator shall date and sign the data collection and take responsibility for the data.

- 5.1.4 Along with the data and their annotations, a guide must be included specifying the structure in which they are stored, the units of quantitative data, the format used in the case of files that must be read by specific software, with the aim that other qualified professionals who have not had access to the development of the project can review the work carried out and reproduce the same results.
- 5.1.5 In general, traceability of the data collection work must be ensured, so that the intellectual property of the results is justified and can be used for review by third parties.
- 5.1.6 If data need to be corrected, this correction shall be documented, including the person responsible for the changes. As far as possible, the original results shall be retained.
- 5.1.7 Records containing information on individuals shall be obtained and stored in compliance with Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights, and any other regulations that may be applicable.

## 5.2 Ownership, custody and storage

- 5.2.1 Unless otherwise contractually agreed, the primary materials obtained in the development of a project (notebooks, raw data, survey forms, etc.) are the property of the institution of affiliation of the principal investigator.
- 5.2.2 In the case of data obtained in collaboration with another institution that grants the use of means, equipment, infrastructures or technical support staff, this institution is co-owner of the data and materials generated, and copies must therefore be made.
- 5.2.3 When a researcher changes their affiliation, they have the right to obtain, upon request to the responsible researchers, a copy of the raw data and materials generated in the projects they were part of in the institution they leave.
- 5.2.4 When the Principal Investigator of a project changes their affiliation, they have the right to keep copies of the raw data and materials generated in the projects they coordinated in the institution they are leaving. This process must be supervised by the Heads of Department, Centre, or Research Institute.
- 5.2.5 There should be infrastructures for the custody and proper preservation of data and materials generated in research. These must be specifically designed to conserve and preserve biological or chemical materials and samples when they require special storage conditions.
- 5.2.6 The USAL is responsible for providing the means for the storage and custody of the data it owns for the stipulated period of time.

- 5.2.7 The recommended period for the conservation of data is a minimum of five years after the date of publication, except in cases where there are regulations, legislation or agreements extending this period. If possible, longer storage times would be desirable.
- 5.2.8 For data stored on electronic media, a redundant storage plan (backup copies) shall be established, and precautions shall be taken against external attacks. Copies of the computer software used to read and process these data shall be stored.
- 5.2.9 Data obtained from or manipulated in research activities should be stored and identified in such a way as to ensure their preservation, access, integrity, and traceability for a reasonable period of time.
- 5.2.10 The original information obtained (samples, questionnaires, recordings, photographs, etc.) must be preserved in their original form prior to processing.
- 5.2.11 Material resulting from the research that is to be exchanged with another institution shall be handled on the basis of written agreements.
- 5.2.12 Data containing personal information as well as human biological samples must be stored in a confidential manner and in compliance with personal data protection regulations and legislation.

### 5.3 Access to and use of data

- 5.3.1 All members of a research team shall have access to the data generated during the project of which they are part for consultation. It is the responsibility of the principal investigator to safeguard, preserve and record access if necessary.
- 5.3.2 When there are no confidentiality restrictions, it is recommended that the data and research results are open access, following the "FAIR" principles (*findability, accessibility, interoperability, and reusability*); it is advisable to provide open access to them and make it easier to cite them.
- 5.3.3 The granting of data or materials to third parties should be done by ensuring traceability of the use of such data. The person or institution requesting the data should therefore identify themselves and state what use they intend to make of these materials or data. If the data are not openly available, access to the data must be approved by the principal investigator. The person making use of these resources must cover the costs of accessing, transporting, or copying them.
- 5.3.4 Along with openly accessible data, a form of acknowledgement of their use must be provided in the communications to which they may give rise.
- 5.3.5 When a researcher uses data or materials outside the project in which they were generated, the researcher shall mention the institution to which they belong in the publications or communications where they are used.

- 5.3.6 When projects are funded with private entities, the policy (ownership and rights) on the use of data and samples generated in the research should be agreed in writing.

## 6. Knowledge Transfer and Scientific Communication

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Communication of results is a highly relevant part of scientific research, as it is not only the main way in which the frontiers of human knowledge are extended, but also one of the main means of accountability of researchers towards funding bodies and society as a whole, as it is the proof of the culmination of the milestones set out in a research project.

The publication of results in peer-reviewed journals is the most widely used means of dissemination, but it is not the only one. Thus, the publication of books, research monographs or chapters in edited books (which are also subject to external peer review by publishers), graphic and poster-type communication at conferences, audiovisual materials, articles in specialised sections of the press, and informative talks aimed at the general public are also noteworthy.

### 6.1 General aspects

- 6.1.1 Research staff should ensure that the results of their research are disseminated and, where appropriate, exploited in accordance with relevant legislation and contractual agreements with funding bodies.
- 6.1.2 Premature reporting of results, i.e., results that have not been published in the relevant specialised media, or that have not undergone a thorough process of external peer review or peer scrutiny, is discouraged.
- 6.1.3 Where there are circumstances (e.g., safety or public health) that justify premature reporting of results, authors should ensure that the results are peer-reviewed by a scientific publisher. Final publishers should be notified of the prior communication and its scope.

- 6.1.4** Excessive and unjustified delay in the publication of results is discouraged when in the course of a research protocol, results of relevance to the scope of a project have been obtained.
- 6.1.5** As an exception, for results with potential commercial interest, publication may be postponed until there are circumstances that secure the industrial property interests (e.g., registration of a patent) of the parties concerned. This should be recognised by the institutions, companies, funding bodies and researchers involved. See **6.2**.
- 6.1.6** Under no circumstances is external pressure from individual interests to speed up or delay submissions, or to alter their scientific content, acceptable.
- 6.1.7** Fragmented publication is discouraged, i.e., the division of a paper into parts that are coherent and correlated with each other. A valid exception applies when this is done for reasons of length.
- 6.1.8** Duplicate or redundant publication practices are discouraged, understood as those involving papers based on the same results and similar analyses and whose difference in terms of contribution to knowledge are minimal.
- 6.1.9** Publication of the same papers or substantial parts of them (including translations) can only be made with the prior permission of the publishers involved, and always including a reference to the first publication.
- 6.1.10** Publication of negative results is a recommended practice in any discipline. However, in clinical or epidemiological studies, publication of negative results is imperative for reasons of public interest.
- 6.1.11** Reporting of results should be preceded by scrutiny by other competent investigators outside the protocol. In peer-reviewed journals (see section **8.1**) this scrutiny is part of the publication process itself.
- 6.1.12** Where research protocols have been subject to oversight and approval by ethics committees or equivalent bodies, this fact should be mentioned in the submissions, especially in the case of peer-reviewed journals.
- 6.1.13** In communications published in scientific articles, books, book chapters or monographs, as well as in contributions to congresses or seminars, when the work has been carried out with funding from public bodies, this support should be acknowledged in a section dedicated to acknowledgements, indicating the funding bodies and the identification of the grants. It is also advisable to include this acknowledgement in reports and technical reports addressed to third parties.
- 6.1.14** In publications in journals, books or monographs, as well as in communications in conferences and dossiers or patents, previous contributions in the field should be acknowledged by means of appropriately contextualised bibliographical references. Likewise, unjustified or honorific references shall be avoided.
- 6.1.15** Partial, unpublished information or data from third parties outside the publication shall also be explicitly acknowledged if permission has been requested and notification of use has been given.

- 6.1.16 Some funders may have policies regarding the dissemination of results (usually aimed at maximising their reach). Principal investigators are responsible for ensuring that these requirements are met.
- 6.1.17 Decisions regarding publication of results should be known to all research staff involved and agreed jointly.
- 6.1.18 Authors must declare conflicts of interest, if any, in making results public.
- 6.1.19 Moral rights concerning the results (acknowledgement of authorship, responsibility for their content, right to correction or retraction) are unwaiverable and inalienable.

## 6.2 Exploitable results

- 6.2.1 The USAL must ensure, through its own bodies and the appropriate legal protection, the rights of researchers in intellectual property matters and with respect to the exploitation of their research results.
- 6.2.2 Similarly, the USAL must ensure its own property rights over the research results obtained in the institution or by its staff, in accordance with the applicable legal regulations and as established in the conditions of the projects and contracts under which they have been developed.
- 6.2.3 As far as possible, the potential industrial or commercial exploitation of the results should be foreseen in the research protocol.
- 6.2.4 The rights of economic exploitation of the results of research projects developed at the USAL by its research staff belong to the institution.
- 6.2.5 Students who produce results or inventions in the course of their academic activity retain the rights to their economic exploitation. When they do so in collaboration with research staff, these exploitation rights will be shared in the proportions agreed upon.
- 6.2.6 In research carried out in collaboration with other institutions or companies, the rights to commercial or industrial exploitation of the results must be established for each of the parties.
- 6.2.7 Researchers shall refrain from any use or dissemination of the results that could prejudice the agreements previously adopted.
- 6.2.8 All authors or inventors of the results will have the right to participate in the possible benefits derived from their exploitation, in accordance with the provisions of the current regulations on the protection of the results and intellectual property of the USAL.
- 6.2.9 When during the course of a project the Principal Investigator detects that the results obtained could be the subject of potential inventions of commercial or industrial interest, this must be communicated to the Vice-Rectorate for Transfer, Innovation and Entrepreneurship through the Office for the Transfer of Research Results, indicating:

- 6.2.9-a) The context in which the result susceptible of exploitation has been produced, including the previous results on which it is based.
  - 6.2.9-b) The commitments that have been assumed with third parties outside the USAL during the development of these results, especially those relating to the confidentiality of information and the exploitation of results (including confidentiality agreements, responsibilities, and rights of all parties).
  - 6.2.9-c) The persons and bodies or entities involved in the generation of the results and in the project in which they are framed.
  - 6.2.9-d) In the case of externally funded research, the regulatory framework within which the project is carried out in accordance with the call for proposals.
- 6.2.10 In the event that the Vice-Rectorate for Transfer, Innovation and Entrepreneurship decides to take action to protect these results:
- 6.2.10-a) These parties will be notified of the decision to protect these results, in order to carry out the subsequent actions in coordination with the parties, safeguarding the rights of all of them.
  - 6.2.10-b) The clauses imposed by the funding bodies that supported the project, if any, will be respected.
  - 6.2.10-c) The staff involved in these results will actively collaborate in the drafting of the necessary documents for their correct protection and subsequent transfer to the socio-economic environment.
  - 6.2.10-d) This is considered an exceptional reason for postponing the communication of results through the public media (see 6.1.5).
- 6.2.11 All authors or inventors participating in these results must opt to participate in the potential benefits derived from the commercial exploitation of these, in accordance with the internal regulations of the USAL.

## 6.3 Authorship and signature of written communications

- 6.3.1 The author of a scientific communication is considered to be all research and technical personnel whose activity has substantially contributed to the development of the communication. The following, among others, are considered as contributions to a paper:
- 6.3.1-a) Participation in the technical tasks (methodologies and procedures) of data collection
  - 6.3.1-b) The design or development of an innovative methodology
  - 6.3.1-c) The processing and interpretation of the data
  - 6.3.1-d) Writing and preparation of the paper

- 6.3.2** All authors must be aware of and endorse the final content of the paper, taking responsibility for it. In addition, each author should be able to describe in detail what their contribution was and how they contributed to the final form of the paper.
- 6.3.3** Where an author cannot take responsibility for the entire content of the paper, they should be identified separately as an author partially responsible for their specific contribution within the possibilities of the medium.
- 6.3.4** Participatory activities through the provision of data, resources, advice, samples, or experimental subjects do not confer author status and are more appropriately considered in an acknowledgements section. When there are parties who provide data, samples or experimental subjects, but do not participate in the development of the protocol or in the activities described in **6.3.1**, it is recommended that a communication and authorship plan agreed upon by all parties be established in advance.
- 6.3.5** Individuals who have contributed significantly to the work, but have not reached the level of authorship, should be acknowledged in the form of acknowledgements, including their names and affiliations. In any case, consideration should be given to the possibility of such contributors declining the option to be mentioned in the acknowledgements; in that case, written permission would be advisable.
- 6.3.6** The inclusion of authors for reasons of professional hierarchy is an ethically inappropriate practice that infringes on academic freedom. Likewise, the inclusion of authors for reasons of honour or through personal relationships is contrary to the criteria set out in **6.3.1**.
- 6.3.7** Similarly, the exclusion of legitimate authors according to the relevance of their contributions in accordance with point **6.3.1** is also an ethically questionable practice and an intellectual misappropriation by the rest of the authors.
- 6.3.8** All communications, technical reports, or reports to third parties must be signed by their authors, and their institutional affiliation must also be reflected.
- 6.3.9** The order of the authors must be decided by agreement, following the criteria considered appropriate according to the field of knowledge. In general, the first signature position is usually given to the author who has carried out most of the work related to the communication, and the last to the author who coordinated the work or the research project, and the order of the rest of the authors may be consensual or alphabetical. The author in charge of the correspondence must be responsible for the editorial process and future communications derived from the paper.
- 6.3.10** When more than one author is considered to have made the same level of effort and contribution, they should be considered as first authors, and this should be reflected in the communication within the editorial possibilities.

- 6.3.11** Researchers will sign according to the [Guide for Spanish researchers for the standardisation of the names of authors and institutions in scientific publications](#) <sup>[7]</sup> prepared by the Spanish Foundation for Science and Technology (Fundación Española para la Ciencia y la Tecnología). In addition, it is considered good practice to use identifiers such as the [Open Researcher & Contributor ID \(ORCID\)](#) <sup>[8]</sup>, [ResearcherID](#) <sup>[9]</sup>, or [Scopus Author Identifier](#) <sup>[10]</sup> to achieve better traceability of the author.
- 6.3.12** In general, in communications coordinated by the USAL, the *Good Practice Guide for Scientific Publications* <sup>[11]</sup> of the Observatory for Academic Quality and Performance will be followed.
- 6.3.1** When, after a publication, errors are detected that entail a loss of value of the results reported, a new publication must be made to correct or amend these results. If these errors are serious, the action to be taken is the retraction of the results. Both actions should be carried out as soon as possible, especially when they concern results of clinical studies.

## 6.4 Open access philosophy

- 6.4.1** USAL recognises authors' intellectual property rights over their research results, while promoting an open philosophy regarding their access, public dissemination and discussion with other researchers, as evidenced by its adherence to the *Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities* <sup>[12]</sup>.
- 6.4.2** Research results and data should be made freely and openly available for consultation by the scientific community. See points and **5.3.1** and **5.3.3**.
- 6.4.3** In order to maximise the dissemination of the results generated under the protection of the USAL, the USAL promotes the principles of [Open Access](#) <sup>[13]</sup>, promoting the availability and free and open access to scientific literature.
- 6.4.4** It is advisable to deposit works derived from scientific research in the [Gredos](#) <sup>[14]</sup> document repository, subject to the possibilities established in the rules of the publishers where they may have been previously published.

## 6.5 Popular dissemination and outreach

- 6.5.1** Dissemination outside the scientific community is considered a responsibility of researchers to maximise the dissemination of their work and accountability to society.
- 6.5.2** The presentation of results in the mass media should be appropriate for non-specialist audiences through an adaptation that uses language of an informative nature.

- 6.5.3 Such communications should aim to build trust in the scientific community by society and demonstrate its commitment to meeting societal challenges, promote dialogue and foster critical thinking and interest in science and research.
- 6.5.4 Dissemination communications should be objective in terms of the impact of their results and the objectives pursued by the lines of research, avoiding over-dimensioning achievements and their implications.
- 6.5.5 Although the expression of opinions by researchers in dissemination activities is not discouraged, these should always be expressed as such, differentiating them from objective facts and scientific evidence.
- 6.5.6 Researchers involved in the dissemination of results obtained through external funding shall comply with the regulations associated with the granting of funds.
- 6.5.7 The USAL will make available to researchers the different institutional means (the [Communication Office](#), the [Scientific Culture Unit](#), the [Diarium](#) blogging platform, the [Gredos](#) repository, etc.) to facilitate the dissemination of their results.
- 6.5.8 In communications intended for the general public, authors should be presented in association with their institutions of affiliation.
- 6.5.9 Whenever possible, the entities that subsidised the grants received for the production of the research on which the dissemination activity is carried out should be mentioned.

## 7. Research Staff

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Nowadays, the complexity that characterises research activity means that in most cases it is essential to approach it by working in teams made up of various specialists and using different methodologies and infrastructures. For this reason, research groups bring together researchers working along similar, overlapping, or complementary lines of research under an organisational structure. However, sometimes the specialists, means and infrastructures needed to tackle ambitious projects transcend the boundaries of a single institution. In this area, good practices are proposed to ensure that the organisation of research staff, research groups and external collaborations guarantee effectiveness and fluidity in the development of their work.

### 7.1 Structure of research groups. Leadership and cooperation

- 7.1.1 All USAL research groups must be identified as such, maintain an updated list of their research members and collaborators and a list of their lines of research. In addition, they must indicate their affiliation with the corresponding Department, Institute or Centre of the USAL.
- 7.1.2 Research groups must include as members those researchers or professors as specified in Arts. 32 and 33. of the regulations of University Research Institutes, Research Centres and Research Groups.
- 7.1.3 Research groups must have an organisational structure that includes the responsibilities of each member with regard to research activities, as well as the appropriate channels of communication.

- 7.1.4** Research groups must promote the development of their members' research activities under the principles of health and safety at work, respect for living beings, environmental and heritage protection, and the proper use of resources, equipment, and facilities. Furthermore, they must disseminate among their members the relevant regulations and standards, as well as this manual of good practice.
- 7.1.5** Each research group must necessarily have a lead researcher, whose functions and responsibilities are<sup>7</sup> (Art 34):
- 7.1.5-a)** To serve as a communication and dialogue link between the USAL and the rest of the members of the research group.
  - 7.1.5-b)** To ensure that the members of the group work in a favourable working environment for the achievement of the common scientific objectives of the group.
  - 7.1.5-c)** To promote collaboration with other research teams, both from the USAL and external entities.
  - 7.1.5-d)** To ensure compliance with the commitments made by the members of the research group in the projects and contracts for which they are responsible or principal investigators.
  - 7.1.5-e)** To manage, record and safeguard access to the data derived from the group's research, also guaranteeing the confidentiality of this data when so agreed.
  - 7.1.5-f)** To collaborate with the relevant USAL research management services when required.
  - 7.1.5-g)** To seek and foster a working environment based on cooperation, the exchange of ideas and knowledge, in order to meet the common research objectives.
  - 7.1.5-h)** To act as mediator in cases of conflict.
- 7.1.6** The proper functioning of the research group is the responsibility of each member, who must take individual responsibility for their professional commitments, as well as collaborate in the creation of a positive working environment.

## 7.2 Recruitment, promotion, and evaluation

- 7.2.1** In the selection processes for the incorporation of researchers, in competitions for access to management bodies and positions of responsibility, and in access to training and retraining activities, the following must be guaranteed:
- 7.2.1-a)** The public dissemination of the selection or promotion processes through the relevant media within deadlines that guarantee timely access to potential interested parties.

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<sup>7</sup> Art. 34 of the Regulations of University Research Institutes, Research Centres and Research Groups.

- 7.2.1-b) Transparency in the selection processes.
  - 7.2.1-c) Equal opportunities, eliminating any discrimination based on gender, race, religion, or other personal conditions.
  - 7.2.1-d) Assessment based on proven merit, in accordance with the statutes and legislation in force.
  - 7.2.1-e) The general principles of Open, Transparent and Merit-based Recruitment (OTMR).
- 7.2.2 There can be no conflict of interest between the evaluator and the person being evaluated. The evaluator must inform the USAL of any such conflicts.

### 7.3 Training and supervision of the trainee researcher

Scientific activity involves learning and the need for continuous training and updating. However, the initial stages of any researcher have a significantly more pronounced formative character, which is crucial for their subsequent professional development. In search of an ideal training stage during the first steps of researchers trained at the USAL, this section includes good practices in the field of tutoring Research Staff in Training.

- 7.3.1 Research Staff in Training (hereinafter RST) are considered to be:
- 7.3.1-a) Those graduates who are developing a pre-doctoral research task (R1) in the framework of a research training programme and within a research group of the USAL.
  - 7.3.1-b) Only for the purposes of this manual, those postdoctoral researchers (R2) whose activity is framed in the execution of a project in which their supervision is specified in the call.
  - 7.3.1-c) Only for the purposes of this manual, those undergraduate or postgraduate students of the USAL who are carrying out research tasks associated with their studies (for example, the development of papers or end-of-degree or end-of-master's degree projects).
  - 7.3.1-d) Only for the purposes of this manual, those beneficiaries of collaboration grants who are carrying out research tasks and are temporarily integrated in USAL research groups.
- 7.3.2 Both the USAL and the host centre of the RST will ensure compliance with the obligations established for them in the [\*Statute of the Research Staff in Training, and in the Regulations of the Statute of the Research Staff in Training on\*](#), and in the [\*Regulations of the Statute of the Research Staff in Training of the University of Salamanca\*](#). Similarly, the RST shall fulfil their own duties.
- 7.3.3 The main regulation for Research Trainees and their Tutors whose activity is part of a Doctoral Programme is, in addition to the above, the [\*Doctoral Regulations of the University of Salamanca\*](#).

- 7.3.4** Any researcher who can be considered as an RST must be properly tutored and supervised. To this end, prior to their incorporation, they must be assigned a tutor or a director in the case of doctoral programmes.
- 7.3.5** The USAL is responsible for offering training support to the RST, through a training offer both transversal and specific, and oriented to the particular needs through the Departments, Centres, and Institutes.
- 7.3.6** When there are conflicts in the relationship between a Researcher in Training and their tutor or director, the former may request the mediation of a third party after informing the Vice-Rector for Research of this circumstance.
- 7.3.7** The obligations of the Researcher in Training are:
- 7.3.7-a)** To form part of the relevant Research Group throughout their training and research period.
  - 7.3.7-b)** To comply with the conditions established in the call for their contract, grant or training programme, fully integrating themselves in the assigned project and assuming the necessary commitments to meet the objectives.
  - 7.3.7-c)** To know and comply with the USAL regulations and other applicable rules.
  - 7.3.7-d)** To follow the indications of their tutor or director, as long as these are not contrary to their own training interests, the conditions established in the contract, grant or training programme, or the established research protocol.
  - 7.3.7-e)** To have regular meetings with their tutor or director, informing them of the results obtained and the progress of their training.
  - 7.3.7-f)** To acknowledge the training and tutoring contribution of their tutor or director in the dissemination of their results.
  - 7.3.7-g)** To carry out their research activity on the basis of the ethical principles of respect for animal life, the environment and heritage, and the protection of personal data, like other research staff.
  - 7.3.7-h)** To make responsible use of the infrastructures, equipment, and facilities necessary for their research and training activities, always in accordance with the rules established by those in charge.
- 7.3.8** The rights of the Researcher in Training are:
- 7.3.8-a)** To have a director or tutor to guide them in their research activity and to coordinate their training activity.
  - 7.3.8-b)** To be integrated into the corresponding Research Institute, Research Centre, Department or Research Group.
  - 7.3.8-c)** To be informed of USAL regulations and other applicable rules.
  - 7.3.8-d)** To have access to and make use of the appropriate infrastructures, facilities, technical resources and workspace in order to be able to carry out their research tasks and training activities.

- 7.3.8-e) To participate in scientific activities (such as congresses, forums, seminars, etc.) that are consistent with their research and training itinerary, and that are considered part of the development of their work.
  - 7.3.8-f) To participate in additional training programmes in accordance with their activity and specialisation that the USAL organises for Teaching and Research Staff.
  - 7.3.8-g) To have their intellectual property rights recognised for the data, findings or communications produced in their research activity.
- 7.3.9 The obligations of the tutor or director of the Researcher in Training are:
- 7.3.9-a) Not to assume the tutoring of more than a maximum number of Researchers in Training in order to allow the compatibility of an adequate educational tutoring of the researchers together with the rest of their academic, professional and institutional obligations.
  - 7.3.9-b) To inform the supervised researcher about the USAL regulations and other applicable rules. In addition, to monitor compliance with these regulations.
  - 7.3.9-c) To ensure that the RST under their supervision can develop their activity in an optimal working environment, ensuring that they have access to the infrastructures, facilities, technical resources, and adequate workspace to carry out their research tasks and training activities.
  - 7.3.9-d) To encourage teamwork, coexistence and participation with the Research Group and the staff of the Department, Centre, or Institute.
  - 7.3.9-e) To interact personally and on a regular basis with the RST in charge in order to supervise and discuss the development of the assigned tasks.
  - 7.3.9-f) To act as a liaison between the research management units and the RST in charge when required.
  - 7.3.9-g) To actively contribute to the scientific, technical, and methodological updating of the RST under their supervision.
  - 7.3.9-h) To carry out their own research work in an exemplary manner, constituting a positive reference point for the RST.
  - 7.3.9-i) To guide and advise the RST under their supervision, respecting their training interests and the conditions established in their contract, grant or training programme.
  - 7.3.9-j) To watch over the working and training conditions of the RST under their supervision, ensuring both their transversal and specific training in terms of health and safety at work.

- 7.3.9-k) To ensure that the RST under their tutelage does not involuntarily or under duress take on tasks or responsibilities unrelated to their training or incompatible with their contractual position.
- 7.3.9-l) To inform the RST under their supervision about the projects in which their potential scientific output is framed, and about the restrictions that apply to its dissemination.
- 7.3.9-m) To acknowledge the contributions of the RST under their supervision to the joint scientific achievements.
- 7.3.9-n) To actively participate in the immersion of the RST in their research career, making them known to other groups in forums, congresses, and scientific meetings, as well as boosting their research profile by stimulating their participation in activities that may be of benefit to them, such as courses, seminars, stays, etc.
- 7.3.9-o) Ultimately, to disseminate this good practice guide to the RST under their supervision.

## 8. Review and Evaluation Activities

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Due to the highly specialised profile of researchers, it is common for them to participate, either individually or through committees, in publication review activities, in the evaluation of protocol and project proposals, or in the assessment of applications for teaching and research positions. Therefore, their research activity is complemented by providing a service to funding bodies or academic institutions, with their verdicts being relevant in matters of professional promotion, research development or the granting of funds for scientific projects. Due to the potential impact of these activities, it is necessary to establish criteria for good practice.

### 8.1 General aspects

- 8.1.1 Professionals involved in review and evaluation tasks must have the training and experience to be able to carry out these tasks with the greatest possible rigour and judgement depending on the field of study of each particular case.
- 8.1.2 For the above reason, invitations to take part in review and evaluation activities should be declined if the person in charge considers that they do not meet these requirements.
- 8.1.3 When professionals invited to take part in review and assessment activities are involved in conflicts of interest with authors, research groups or candidates, they must inform the publisher, the institution or the competent authority and decline such participation.

- 8.1.4** Review and evaluation activities are considered confidential. Therefore, the privileged use of information contained in publications, project reports or protocols, as well as the dissemination of information derived from reviews or evaluations, must be avoided. For the same reason, the copying of information is discouraged and its destruction after the end of the review or evaluation work is recommended.
- 8.1.5** The USAL encourages the participation of its researchers in the tasks of peer review of publications, evaluation of projects in public calls, selection of candidates for teaching and research positions, and evaluation of research groups, departments, and organisations.

## **8.2 Peer review of publications and project evaluation**

- 8.2.1** The main objective of a peer review process is to subject a scientific communication and its results to scrutiny to ensure that they are reliable and have been achieved with the utmost rigour, and ultimately to determine whether they are suitable for publication. This ensures a high standard of scientific quality in publications.
- 8.2.2** Researchers should decline to review a paper if they feel that their knowledge and experience are not sufficiently broad or deep enough to warrant their suitability as a reviewer of the paper.
- 8.2.3** Criticism of a review should be objective and always based on scientific criteria. In addition, they should, as far as possible, be accompanied by supporting bibliographical references.
- 8.2.4** Using the opportunity to serve as a reviewer to obtain bibliographic citations that are not appropriate in the context of the work under review should be avoided.
- 8.2.5** It is good practice to offer criticism and demands in a constructive spirit, with the aim of raising the standard of the publication, such as requesting changes to clarify less understandable parts, requesting more details about the methodology used, bibliographical suggestions, additions of supplementary material, etc.
- 8.2.6** Confidentiality regarding the content of a peer review publication is maintained until the manuscript is published or withdrawn.

## **8.3 Evaluation of projects and protocols**

- 8.3.1** The evaluation for project funding will be based on the principles of potential social impact, scientific-technological relevance, validity of the methodology, risk-benefit balance and overall feasibility of the project as a whole.

- 8.3.2 The use by an evaluator of ideas, procedures or methodologies reflected in a research project submitted for evaluation is considered as intellectual misappropriation.
- 8.3.3 The conclusions of project and protocol evaluations should be reasoned, objective and understandable. Preferably they should be made available to the project leaders by the funding agencies.
- 8.3.4 Investigators in charge of reviewing a research project who detect malpractice or unidentified ethical conflicts should report this confidentially to the entity requesting the review.

## 8.4 Assessment of applications

- 8.4.1 Evaluations of candidates for research positions will be conducted on the principles of transparency, merit-based assessment, fairness, and equity.
- 8.4.2 The main element of evaluation of a candidate must be their *curriculum vitae*, which must truthfully and provably compile all achievements that can be considered as merits for that candidature.
- 8.4.3 The evaluation criteria must be clear, defined prior to the admission of candidates and described in such a way that there is minimal room for interpretation and subjectivity in the assessment of merit.
- 8.4.4 In all evaluations of candidates for technical or research staff, the rights of candidates to dignity, confidentiality of their data and respect for their privacy shall be respected.
- 8.4.5 Once the evaluation processes have been completed, the initial decision shall be made known to the candidates, informing them of the result on an individual basis, as well as by means of public communication on the institutional notice board. In addition, a period of allegations will be allowed.

## 9. The Institutional Environment

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The USAL, as an institution dedicated to university teaching and scientific research, is responsible for providing an environment that is stimulating for its professionals. For their part, researchers are also responsible for promoting these values in their immediate environment and for collaborating with the institution to achieve this objective. This section contains the institutional commitments and recommendations to researchers aimed at facilitating compliance with this manual.

### 9.1 Institutional commitment

- 9.1.1 The USAL will maintain an updated public list that includes the research lines of the different research groups, their active projects with the relevant acknowledgements to the funding bodies, the main objectives, the human team responsible, the collaborations established with other institutions and the communications and knowledge transfer.
- 9.1.2 The USAL and its research staff are responsible for promoting a favourable environment for the development of research based on ethical principles, professionalism, cooperation, exchange of ideas, honesty, and social commitment.
- 9.1.3 The USAL and its research staff must ensure compliance with the legal and ethical requirements applicable to their research activity. This involves submitting applications and complying with reports for ethical review, as well as being certain that research projects have the approval of all relevant bodies.
- 9.1.4 USAL research staff who carry out research work in other centres must comply with the ethical and legal commitments of the USAL, as well as those relating to the centre where they carry out these tasks. Likewise, researchers from outside the USAL who carry out tasks in its facilities must comply with the same ethical and legal commitments as USAL staff.

- 9.1.5** The USAL is responsible for providing the means that allow research data to be stored and guarded in an efficient, secure, and accessible manner, facilitating its management to the researcher in charge.
- 9.1.6** It is the responsibility of the USAL:
- 9.1.6-a)** To promote good practices by including them in its research policy and to ensure that these policies are compatible with mandatory regulations.
  - 9.1.6-b)** To provide the necessary mechanisms and resources to facilitate the development of research in accordance with the good practices set out in this manual.
  - 9.1.6-c)** To establish clear policies and procedures that cover the principles of good practice in research and to provide information and training on the established standards to their research staff.
  - 9.1.6-d)** To establish information channels for research staff on policies, regulations and procedures related to research ethics.
  - 9.1.6-e)** To involve research staff in this good practice, encouraging their collaboration in its continuous improvement.
  - 9.1.6-f)** To regulate the approval and conditions for the hiring of personnel or the acquisition of material, equipment, or specific infrastructures.
  - 9.1.6-g)** To promote research excellence through the continuous training of its staff so as to enable them to carry out their research tasks in optimal conditions and with up-to-date knowledge, as well as to fully exploit their skills and abilities.
  - 9.1.6-h)** To provide the research community with specialised services in economic and technical management, legal advice, human resources, ethics, and research integrity.
- 9.1.7** On the other hand, it is the responsibility of the research staff as a whole:
- 9.1.7-a)** To assume the ethical commitments that the development of their research activity may entail.
  - 9.1.7-b)** To carry out their research and supervisory activity applying the policies and good practices in research at the USAL, seeking support and assistance from the relevant bodies when necessary.
  - 9.1.7-c)** To collaborate with the USAL in the compliance, dissemination and updating of the Manual of Good Practice and the regulations on research ethics.
  - 9.1.7-d)** To request approval from the corresponding USAL bodies for the hiring of personnel, or for the acquisition of material, equipment, or specific infrastructures.

## 9.2 Action contrary to the manual and conflict resolution

In the same way that the previous sections have established rules of good practice, it is advisable to include those practices that should be avoided, as they are outside all scientific and professional ethics. This section includes the most relevant ones.

**9.2.1** The following are considered bad practices in research:

- 9.2.1-a) The fabrication, falsification, alteration, or concealment of research results.
- 9.2.1-b) Copying or plagiarism – also understood as the omission of quotations where appropriate – and the appropriation of ideas, work, or data from other colleagues.
- 9.2.1-c) Failure to declare conflicts of interest and the performance of any evaluation or review task whose outcome may have been altered by such conflicts.
- 9.2.1-d) Inappropriate expenditure of research funds and fraudulent justification of expenditure on projects or contracts.
- 9.2.1-e) The execution of research protocols that may involve ethical conflicts without prior approval from the competent bodies.
- 9.2.1-f) The unjustified blocking of the use of materials, facilities, means or research infrastructures by those responsible (individuals, Centres, Institutes, Departments or Research Groups).
- 9.2.1-g) Inappropriate storage of data or materials produced in research and practices that prevent access to them.
- 9.2.1-h) Unjustified non-publication of results, and also duplicate or fragmentary publication without due justification.
- 9.2.1-i) Deliberate omission of reference to other relevant work or external research data, as well as honorific or out-of-place citation.
- 9.2.1-j) Delay or obstruction of the work of other researchers.
- 9.2.1-k) Use of improper procedures that may involve excessive or unjustified risk or harm to human subjects, animals used in research, or the environment.
- 9.2.1-l) Inappropriate use of privileged or private information of individuals gathered during the research.
- 9.2.1-m) In general, any action contrary to the contents of this Manual of Good Practice in Research.

**9.2.2** It is also considered bad practice to carry out tasks when there is a conflict of interest. Research staff must take responsibility for acknowledging and disclosing conflicts of interest that may interfere with the performance of their duties in research, tutoring, evaluation of applications, project proposals, and peer review of the work of other researchers.

- 9.2.3** Research staff are responsible for not engaging in such misconduct, for complying with this manual and for using appropriate mechanisms for the detection, reporting and elimination of misconduct.
- 9.2.4** The USAL will establish clear policies for dealing with conflicts of interest, including the necessary guidance and means for research staff to identify and report them.
- 9.2.5** All members belonging to the university community are entrusted with reporting any case of malpractice in research of which they are aware to the Vice-Rectorate for Research, which will manage the conflict by setting up a committee made up of professionals of recognised impartiality and will inform the researchers responsible of the existence of this circumstance and the channels available for its resolution.
- 9.2.6** Conflict resolution and the search for solutions must be carried out with strict confidentiality, always offering fair treatment to all parties and with the aim of seeking the highest quality of research and harmony in the working environment.

## 9.3 Research Ethics Committee


The most relevant body that the USAL makes available to the research staff of the institution with regard to the evaluation of the ethical, methodological and legal aspects of the research and teaching activities carried out at the University of Salamanca is the Research Ethics Committee (REC). (<https://investigacion.usal.es/es/comite-bioetica>).

- 9.3.1** The REC is a body that acts at the service of all the Research Groups, Research Institutes or Centres attached to the University of Salamanca. It is responsible for evaluating research projects carried out by researchers linked to any of these centres and involving interventions on human beings, the use of biological samples of human origin, the use of personal data and the use of animals in research and teaching.
- 9.3.2** The REC has its own regulations, which establish its functions, the number and hierarchy of its members, the requirements they must fulfil, the periods and procedure for their renewal, its organisation and operation.
- 9.3.3** Its functions are:
- 9.3.3-a)** To evaluate research projects with correctness, equanimity, respect and efficiency.
  - 9.3.3-b)** To monitor animal experimentation projects requiring retrospective evaluation in accordance with the provisions of current legislation.
  - 9.3.3-c)** To develop Recommendations and Good Practice Guidelines and training tasks in research ethics to facilitate the work of the staff.
  - 9.3.3-d)** Any other function established in the current regulations aimed at ensuring ethics in research.

- 9.3.4** The REC makes available to the research community on its website the necessary tools to validate protocols subject to ethical or safety issues. Researchers are responsible for using these tools in the development of protocols that require approval due to ethical or safety issues.

## 9.4 Dissemination, revision and updating of the manual

The USAL acknowledges its responsibility to ensure that this manual is distributed to its research community and that it reaches its addressees, as well as third parties that may be involved in research work with the USAL. It is also the responsibility of the USAL to keep this manual up to date, promoting its periodic revision by its own personnel specially designated for this purpose.

- 9.4.1** The USAL will provide the means for the dissemination of this manual, guaranteeing its access to the interested agents as stated in [section 1](#).
- 9.4.2** The manual will be available on the USAL Research portal website (<https://investigacion.usal.es> ) and the Research Institutes and Specialised Centres will also be recommended to link it from their websites.
- 9.4.3** The secretaries of the Departments and the Directors of the Specialised Centres and Research Institutes will distribute the new manual to all their staff. Similarly, it will be made available to new staff upon their incorporation.
- 9.4.4** This manual will be mentioned and linked in the welcome manual for researchers joining the institution.
- 9.4.5** The USAL will ensure through its governing bodies that the contents of this manual are regularly analysed and discussed with the involvement of the USAL research community.
- 9.4.6** The Research Council<sup>8</sup> is responsible for the effective review of this manual and must propose by consensus any improvements or changes it deems appropriate, which must subsequently be positively assessed by the Research Council itself.

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<sup>8</sup> See Art. 111 of the Statutes of the USAL.

## ANNEXES

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## Annex I. Reference Documents

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### Documents on which this manual is based











- ▶ The European Code of Conduct for Research Integrity  
[https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics\\_code-of-conduct\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf)   
<https://allea.org/code-of-conduct> 
- ▶ Ethics & Principles for Science & Society Policy-Making: The Brussels Declaration  
<https://www.sci-com.eu/main/docs/Brussels-Declaration.pdf?58b6e4b4> 
- ▶ Code of Good Scientific Practices of CSIC  
[https://www.csic.es/sites/default/files/2023-01/cbpc\\_csic2021.pdf](https://www.csic.es/sites/default/files/2023-01/cbpc_csic2021.pdf) 
- ▶ National Declaration on Scientific Integrity (CRUE)  
<https://www.crue.org/wp-content/uploads/2020/02/Declaraci%C3%B3n-Nacional-Integridad-Cient%C3%ADfica.pdf> 
- ▶ Ethics for Researchers. Facilitating Research Excellence in FP7  
[https://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers\\_en.pdf](https://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf) 
- ▶ Declaration on research integrity in responsible research and innovation  
[https://www.researchgate.net/publication/309583324\\_Declaration\\_on\\_research\\_integrity\\_in\\_responsible\\_research\\_and\\_innovation](https://www.researchgate.net/publication/309583324_Declaration_on_research_integrity_in_responsible_research_and_innovation) 
- ▶ Singapore Statement on Research Integrity  
<https://wcrif.org/guidance/singapore-statement>  (English )
- ▶ Montreal Statement on Research Integrity  
<https://wcrif.org/guidance/montreal-statement>  (English , Spanish )
- ▶ Statement on Science and the Use of Scientific Knowledge  
[https://unesdoc.unesco.org/ark:/48223/pf0000116994\\_spa](https://unesdoc.unesco.org/ark:/48223/pf0000116994_spa) 

- ▶ Recommendations of the Ethics Committee for Research in Spain regarding the promotion and implementation of Good Scientific Practices in Spain  
[https://www.ehu.es/documents/2458096/2699121/VIIIe\\_CBE\\_recomendacion\\_es\\_bp.pdf](https://www.ehu.es/documents/2458096/2699121/VIIIe_CBE_recomendacion_es_bp.pdf)
- ▶ Guide to help Spanish researchers standardise the names of authors and institutions in scientific publications  
[https://www.recursoscientificos.fecyt.es/sites/default/files/2015\\_02\\_16\\_normalizacion\\_nombre\\_autor.pdf](https://www.recursoscientificos.fecyt.es/sites/default/files/2015_02_16_normalizacion_nombre_autor.pdf)
- ▶ Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities  
<https://openaccess.mpg.de/Berlin-Declaration>
- ▶ Scientific articles: Who can sign them and in what order. Ethics and pragmatism in scientific publishing  
<https://doi.org/10.14201/orl.19620>

## Other institutional standards and guidelines

- ▶ Agreement 19/2003 of 30 January, of the Regional Government of Castile and Leon, approving the Statutes of the University of Salamanca  
<https://www.usal.es/files/estatutos.pdf>
- ▶ Code of Ethics and Good Governance of the University of Salamanca  
[https://www.usal.es/files/codigo\\_etico-octubre2019.pdf](https://www.usal.es/files/codigo_etico-octubre2019.pdf)
- ▶ Guide to Good Practice in Scientific Publications  
<https://Indicadores.usal.es/portal/guia-de-buenas-practicas-para-publicaciones-cientificas>
- ▶ Regulations of the Statute of the Research Staff in Training of the University of Salamanca  
[http://secretaria.usal.es/boletines/consulta/files/6502-P08\\_Propuesta\\_Reglamento\\_Estatuto\\_PIF\\_USAL.pdf](http://secretaria.usal.es/boletines/consulta/files/6502-P08_Propuesta_Reglamento_Estatuto_PIF_USAL.pdf)
- ▶ Doctoral Regulations of the University of Salamanca  
[http://secretaria.usal.es/boletines/consulta/files/7407-P05\\_CG\\_Modif\\_Reglamento\\_Doctorado\\_20150129.pdf](http://secretaria.usal.es/boletines/consulta/files/7407-P05_CG_Modif_Reglamento_Doctorado_20150129.pdf)
- ▶ Regulations of University Research Institutes, Specialised Centres, Research Groups and Units of Excellence  
[http://documentmanager.usal.es/boletines/consulta/files/10634-Reglamento\\_Institutos\\_GIR\\_UE\\_2020.pdf](http://documentmanager.usal.es/boletines/consulta/files/10634-Reglamento_Institutos_GIR_UE_2020.pdf)
- ▶ Regulations on Patents and other Industrial Property Rights of the University of Salamanca (Approved at the ordinary session of the Governing Council on 21 December 2016)  
<https://www.usal.es/reglamento-de-patentes-y-otros-derechos-de-propiedad-industrial-de-la-universidad-de-salamanca>




## National laws and regulations

- ▶ Law 14/2011, of 1 June, on Science, Technology, and Innovation  
<https://www.boe.es/buscar/act.php?id=BOE-A-2011-9617> 
- ▶ Royal Decree 99/2011, of 28 January, regulating official doctoral studies  
<http://www.boe.es/buscar/act.php?id=BOE-A-2011-2541> 
- ▶ Royal Decree 103/2019, of 1 March, approving the Statute of pre-doctoral research staff in training  
[https://www.official state bulletin.es/diary\\_boe/txt.php?id=boe-A-2019-3700](https://www.official state bulletin.es/diary_boe/txt.php?id=boe-A-2019-3700) 
- ▶ Royal Decree 2245/1986 of 10 October, approving the Regulations for the implementation of Law 11/1986 of 20 March, on Patents  
<http://www.boe.es/buscar/pdf/1986/BOE-A-1986-28777-consolidado.pdf> 
- ▶ Law 23/2006, of 7 July, which amends the revised text of the Intellectual Property Law, approved by Royal Legislative Decree 1/1996, of 12 April  
<https://www.boe.es/boe/dias/2006/07/08/pdfs/A25561-25572.pdf> 
- ▶ Royal Decree 53/2013 of 1 February, establishing the basic rules applicable to the protection of animals used for experimental and other scientific purposes, including teaching.  
[https://www.boe.es/diario\\_boe/txt.php?id=BOE-A-2013-1337](https://www.boe.es/diario_boe/txt.php?id=BOE-A-2013-1337) 
- ▶ Law 32/2007 of 7 November on the care of animals in their exploitation, transport, experimentation and sacrifice.  
<https://www.boe.es/eli/es/l/2007/11/07/32/con> 
- ▶ Order ECC/566/2015 of 20 March establishing the training requirements to be met by personnel handling animals used, bred or supplied for experimental and other scientific purposes, including teaching  
<https://www.boe.es/eli/es/o/2015/03/20/ecc566> 
- ▶ Royal Decree 1386/2018, of 19 November, amending Royal Decree 53/2013, of 1 February, laying down the applicable basic rules for the protection of animals used in experimentation and other scientific purposes, including teaching  
<https://www.boe.es/eli/es/rd/2018/11/19/1386> 
- ▶ Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, concerning the protection of natural persons with regard to the processing of personal data and the free movement of such data and repealing Directive 95/46/EC  
<https://eur-lex.europa.eu/legal-content/ES/TXT/?uri=CELEX:32016R0679> 
- ▶ Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the Guarantee of Digital Rights  
<https://www.boe.es/eli/es/lo/2018/12/05/3/con> 
- ▶ Royal Decree 1369/2000, of 19 July, amending Royal Decree 822/1993, of 28 May, establishing the principles of good laboratory practice and its application in the conduct of non-clinical studies on substances and chemicals.  
<https://www.boe.es/eli/es/rd/2000/07/19/1369> 




## Clinical research policy

This section contains a list of regulations applicable in the field of clinical research. It should be noted, however, that it is neither exhaustive nor completely up to date.

In the event that members of the University community detect any absence, obsolescence, or errors in this list, they are invited, in accordance with section 9.4, to send their suggestions to the Vice-Rectorate for Research.

- ▶ Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, the Ethics Committees for Research with medicinal products and the Spanish Register of Clinical Trials  
<https://www.boe.es/eli/es/rd/2015/12/04/1090> 
- ▶ Law 14/2007, of 3 July, on Biomedical Research  
<https://www.official.state.bulletin.es/eli/es/l/2007/07/03/14> 
- ▶ Royal Decree 1716/2011, of 18 November, which establishes the basic requirements for the authorisation and operation of biobanks for biomedical research purposes and the treatment of biological samples of human origin, and regulates the operation and organisation of the National Register of Biobanks for biomedical research  
<https://www.boe.es/eli/es/rd/2011/11/18/1716> 
- ▶ Law 41/2002, of 14 November, Basic Regulation of Patient Autonomy and Rights and Obligations in Clinical Information and Documentation  
<https://www.boe.es/eli/es/l/2002/11/14/41/con> 

## Other references

- ▶ Transparency Agreement on the Use of Animals in Scientific Experimentation in Spain  
<https://cosce.org/acuerdo-de-transparencia> 
- ▶ M. Balls. "The three RS and the humanity criterion: reduction, refinement, replacement", FRAME (Nottingham - UK, 2009) ISBN 978-0950170022
- ▶ M. S. Davis, M. Riske-Morris, S. R. Diaz. "Causal factors involved in research misconduct: Evidence from ORI case files", *Science and Engineering Ethics* **13(4)**, p. 395-414 (2013)  
<https://doi.org/10.1007/s11948-007-9045-2> 
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